K131626

FEB 26 2014

510(k) Summary
Exceleron Bacterial Filter

Date Prepared: May 30, 2013 (Revised Feb 26, 2014)

Submitter: Exceleron Medical
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Proprietary Name: Exceleron Bacterial Filter (See table below for specific models)

Common/Usual Name: Breathing Circuit Bacterial Filter

PROPRIETARY NAME	COMMON NAME
DBX32	Bacterial Intake Filter
DBX24	Bacterial Intake Filter
DBX25xx	Bacterial Intake Filter
DBXEFLO	Bacterial Intake Filter
BDF47xx	Bacterial Patient Filter

Classification Name: Breathing Circuit Bacterial Filter, Class II, Product Code CAH
21 CFR 868.5260

Establishment Registration Number: 3007709321

Description:
A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases in the breathing circuit of a respiratory device. The filter is a replaceable accessory device used in oxygen concentrators, either as intake filters or final patient filters. The function of the oxygen concentrator machine is to draw room air into the machine's compressor and concentrate the oxygen content before delivering filtered, oxygen rich air to the patient. From the compressor, the filtered air proceeds to the sieve beds. The sieve beds in the oxygen concentrator machine condition the air, by removing nitrogen from the air stream, which results in a higher concentration of oxygen. The air then passes through the final patient filter before being supplied to the patient. The Exceleron Medical bacterial intake filter and the final patient filter are intended to remove air borne bacteria and other particulate debris from the air stream.

Indications for Use:
Exceleron Medical bacterial filters are single use replacement filters intended for use in oxygen concentrator machines to help remove contaminants, including air borne bacteria and other particulate debris from an air stream. When used with oxygen concentrator machines, the replacement filters may be used in the home, nursing home, hospital, patient care facility.

Substantial Equivalence:
The Exceleron Bacterial Filter is substantially equivalent to the following predicate devices:

- AG Industries Bacterial Filters K091363
- Porous Media Oxygen Concentrator Filters K061426

Technological Characteristics:
Technically from a design and mechanism of action standpoint, the Exceleron Bacterial Filters are substantially equivalent to the predicate devices. All utilize a dimensionally equivalent molded housing containing glass microfiber filtration material with appropriate connector fittings for attachment to the applicable breathing circuit. Exceleron Bacterial Filters and the predicate devices have the same principle of operation and mechanism of action, namely air flows through the glass microfiber bed to remove contaminants, including air borne bacteria and other particulate debris.

All the filters are designed as replacement filters for use on oxygen concentrator machines, such as DeVilbiss, Respironics, and Invacare.

Biocompatibility:
The bacterial filter is a tissue contact device that filters the air delivered to the patient. As a result, a systematic risk analysis and biological evaluation were conducted in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. The device was categorized as a tissue contact device with limited duration contact due to the dry gas pathway. As such the following tests were conducted per ISO 10993-1: cytotoxicity, sensitization and intracutaneous reactivity. This testing showed that the Exceleron Bacterial Filter devices meet the biocompatibility requirements for their intended use.

Performance Bench Testing:
Design verification testing was performed for the Exceleron Bacterial Filter to demonstrate physical and functional requirements were met. Testing included bacterial filtration efficiency (BFE) at an increased challenge and air flow resistance. All tests were successful. The Exceleron filters demonstrated BFE capabilities from 99.9% to 99.999%, which are in the same range as the predicate BFE numbers, and air flow resistance was comparable or less than the comparable products, demonstrating substantial equivalence.

Conclusion:
Through the data and information presented, Exceleron Medical, considers the Bacterial Filters substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design, materials, principle of operation and functional performance and present no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Exceleron Medical
C/O Mr. Bernard Horwath
HRG
4486 Timberline Ct
Vadnais Heights MN 55127

Re: K131626

Trade/Device Name: Exceleron Bacterial Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: January 24, 2014
Received: January 28, 2014

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131626

Device Name
Exceleron Bacterial Filter

Indications for Use *(Describe)*
Exceleron Medical bacterial filters are single use replacement filters intended for use in oxygen concentrator machines to help remove contaminants, including air borne bacteria and other particulate debris from an air stream. When used with oxygen concentrator machines, the replacement filters may be used in the home, nursing home, hospital, patient care facility.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Anya C. Harry -S
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